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DOUGLAS E OLSON
LYON & LYON
SUITE 4700
633 WEST FIFTH STREET
LOS ANGELES CA 90071

EXAMINER	
MARSCHEL, A	
ART UNIT	PAPER NUMBER
1809	

DATE MAILED: 01/07/97

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.

08/454,529

Applicant(s)

Hogan et al.

Examiner

Ardin Marschel

Group Art Unit

1809

☒ Responsive to communication(s) filed on

9/6/96

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 330-485 is/are pending in the application.

Of the above, claim(s) 1-329 ~~is/are withdrawn from consideration.~~ have been canceled

☐ Claim(s) _____ is/are allowed.☒ Claim(s) 330-485 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claims _____ are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☒ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number) _____☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☐ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1809.

Applicants' arguments, filed 9/6/96, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

A substitute specification is required because the amendments to the specification, filed 9/6/96, are so numerous that entry thereof would result in so many changes that accurate printing of the amended specification is unlikely of any patent that may be allowed from this application. This amendment has not been entered. The substitute specification filed must be accompanied by a statement that it contains no new matter. Such statement must be a verified statement if made by a person not registered to practice before the Office.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does

not provide support for the invention as is now claimed.

The instant claims contain NEW MATTER regarding the citation of numerous specific rRNA sequence regions from which probes may be prepared because the citations are broader in scope than the scope with which these regions were disclosed as originally filed. For example, instant claim 330 cites bases 65-108 of E. coli 5S rRNA as being a generic region from which a probe should be selected by sequence comparison between a generic targeted species vs. a non-target species. By contrast, this region was disclosed as filed on page 55, lines 15-19, as being found to be selective between a targeted M. pneumoniae and several non-targeted species given as M. gallisepticum etc. Consideration of the disclosure as filed has not revealed a written description of utilizing this 65-108 region for the "generic" selection of probes that distinguish generic targeted from generic non-targeted species. This broadening of scope that is now contained in claim 330 is NEW MATTER. Other sequences in claim 330 suffer from this NEW MATTER broadening of scope. Another example is given as the 16S region as bases 820-860 which is disclosed as filed in original claim 97 but therein directed to M. pneumoniae rather than generically as now given in instant claim 330. Yet another example is the 60-105 region of 16S rRNA which is directed to Chlamydia trachomatis in original claim 137. It is acknowledged that several regions are cited in originally filed claims as directed to non-viral species which may reasonably be interpreted as ribosomal RNA or DNA sequence containing species.

These regions that have basis as filed are given as follows:

- 16S region at bases 170-230 (original clm 306)
- 16S region at bases 405-480 (original clm 308)
- 16S region at bases 600-670 (original clm 310)
- 16S region at bases 820-860 (original clm 312)
- 16S region at bases 980-1050 (original clm 314)
- 16S region at bases 1250-1290 (original clm 316)
- 23S region at bases 270-390 (original clm 318)
- 23S region at bases 535-560 (original clm 320)
- 23S region at bases 1150-1200 (original clm 322)
- 23S region at bases 1440-1600 (original clm 324)
- 23S region at bases 1710-1750 (original clm 326)
- 23S region at bases 2190-2330 (original clm 328)

Applicant is requested to point to support for each rRNA region as to a disclosure that supports the presently pending claims. Claim 330-485 also contain NEW MATTER because genus differentiation was not described as to a written description by stating "non-viral" which is not deemed to be limited as to genus differentiation per se. In other words another issue of NEW MATTER is that the instant claims are not limited to non-viral species whereas this is a limitation as filed. This rejection is necessitated by amendment.

Claims 330-485 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the above objections to the specification.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee of \$ 730.00 for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

If applicant has filed multiple proposed amendments which,

when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 305-3014 or (703) 308-4227.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliot, can be reached on (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

January 6, 1997

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER
GROUP 1800